

**INFORMATION DISCLOSURE STATEMENT**

Applicant : Cheng, et al.  
App. No : 10/518,223  
Filed : December 15, 2004  
For : PHARMACEUTICAL PREPARATION  
AND METHOD OF TREATMENT OF  
HUMAN MALIGNANCIES WITH  
ARGININE DEPRIVATION  
Examiner : Iqbal Hossain Chowdhury  
Art Unit : 1652

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

March 8, 2006

(Date)

  
Suzanne G. Jepson, Reg. No. 51,848

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:


Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing thirty (30) references to be considered by the Examiner. Also enclosed are twenty-eight (28) foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 8, 2006

By:   
Suzanne G. Jepson  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 2

Application No.	10/518,223
Filing Date	December 15, 2004
First Named Inventor	Ning Man Cheng
Art Unit	1652
Examiner	Iqbal Hossain Chowdhury
Attorney Docket No.	EAGIP5.001APC

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	6,261,557 B1	07-17-2001	Tepic, et al.	
	2	6,316,199 B1	11-13-2001	Vockley, et al.	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	3	EP 0 956 864 A1	11-17-1999	Kyowa Hakko Kogyo Co., Ltd.		
	4	WO 98/06421	02-19-1998	Cancer Treatments International		
	5	WO 99/43345 A1	09-02-1999	Eisai Co., Ltd.		
	6	WO 02/09766 A1	02-07-2002	Park, et al.		
	7	WO 02/024156 A3	03-28-2002	Henkel Kommanditgesellschaft Auf Aktien		
	8	WO 02/44360 A2	06-06-2002	Phoenix Pharmacologics, Inc.		
	9	WO 2003/063780 A3	08-07-2003	Cancer Treatments International		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	10	Baillie, et al. 1998. A heat-inducible <i>Bacillus subtilis</i> bacteriophage $\Phi$ 105 expression system for the production of the protective antigen of <i>Bacillus anthracis</i> . <i>FEMS Microbiology Letters</i> , 163:43-47.	
	11	Colleluori, et al. 2001. Expression, purification, and characterization of human type II arginase. <i>Archives of Biochemistry and Biophysics</i> , 389(1):135-143.	
	12	Haraguchi, et al. Created June 7, 1987; last updated, Version 5, March 4, 2000. Molecular cloning and nucleotide sequence of cDNA for human liver arginase. Database accession no. M14502, abstract. XP-002258160.	
	13	Haraguchi, et al. 1987. Molecular cloning and nucleotide sequence of cDNA for human liver arginase. <i>Proc. Natl. Acad. Sci. USA</i> . 84:412-415.	
	14	Harris, et al. Pegylation: A novel process for modifying pharmacokinetics. <i>Clin. Pharmacokinet</i> , 40:539-551.	

Examiner Signature	Date Considered
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

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SHEET 2 OF 2

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	15	Ikemoto, et al. 1989. Purification and properties of human erythrocyte arginase. <i>Ann. Clin. Biochem.</i> , 26:547-553.	
	16	Ikemoto, et al. 1990. Expression of human liver arginase in <i>Escherichia coli</i> . <i>Biochem. J.</i> , 270:697-703.	
	17	Lamb, et al. 2000. Single amino acid (arginine) deprivation induces G1 arrest associated with inhibition of Cdk4 expression in cultured human diploid fibroblasts. <i>Experimental Cell Research</i> , 255:238-249.	
	18	Lea, et al. 1993. Inhibitory effect of arginine restriction on hepatoma growth. <i>Cancer Biochem. Biophys.</i> , 13(3):171-179.	
	19	Leung, et al. 1995. Characterization of an insertion in the phage $\Phi$ 105 genome that blocks host <i>Bacillus subtilis</i> lysis and provides strong expression of heterologous genes. <i>Gene</i> , 154:1-6.	
	20	Malumbres, et al. 2001. To cycle or not to cycle: A critical decision in cancer. <i>Nature Reviews</i> , 1:222-231.	
	21	Özer, N. 1985. A new enzyme-coupled spectrophotometric method for the determination of arginase activity. <i>Biochemical Medicine</i> , 33:367-371.	
	22	Savoca, et al. 1979. Preparation of a non-immunogenic arginase by the covalent attachment of polyethylene glycol. <i>Biochimica et Biophysica Acta.</i> , 578:47-53.	
	23	Savoca, et al. 1984. Cancer therapy with chemically modified enzymes. II. The therapeutic effectiveness of arginase, and arginase modified by the covalent attachment of polyethylene glycol, on the taper liver tumor and the L5178Y murine leukemia. <i>Cancer Biochem Biophys.</i> , 7:261-268.	
	24	Scott, et al. 2000. Single amino acid (arginine) deprivation: Rapid and selective death of cultured transformed and malignant cells. <i>British Journal of Cancer</i> , 83(6):800-810.	
	25	Storr, et al. 1974. The effects of arginine deficiency on lymphoma cells. <i>British Journal of Cancer</i> , 30:50-59.	
	26	Thornewell, et al. 1993. An efficient expression and secretion system based on <i>Bacillus subtilis</i> phage $\Phi$ 105 and its use for the production of <i>B. cereus</i> $\beta$ -lactamase I. <i>Gene</i> , 133:47-53.	
	27	Wheatley, et al. 2000. Single amino acid (arginine) restriction: Growth and death of cultured HeLa and human diploid fibroblasts. <i>Cellular Physiology and Biochemistry</i> , 10:37-55.	
	28	Examination Report from New Zealand Patent Application No. 537774 dated March 11, 2005.	
	29	International Preliminary Examination Report from PCT/GB03/02665 dated July 20, 2004.	
	30	Written Opinion from PCT/GB03/02665 dated March 22, 2004.	

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030606

Examiner Signature

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